Oncology Update

Fall 2020

Thomas Zusag, MD;
Carlene Springer, APRN; and
M. Sitki Copur, MD FACP

Mary Lanning HEALTHCARE
Morrison Cancer Center

A quarterly newsletter from Mary Lanning Healthcare's Morrison Cancer Center
Local and national cancer authority
The definition of excellence in a comprehensive, academic, community cancer program.

MCC contributes to ASCO guidelines

Dr. M. Sitki Copur participated in the American Society of Clinical Oncology (ASCO) expert panel recently. The panel included national and international opinion leaders and authorities who updated the Metastatic Pancreatic Cancer Guidelines.

The panel, including Dr. Copur, reviewed new advancements in the field and made timely updates to the guidelines. Dr. Copur has served on the panel since 2014. The update was published in the August 5, 2020, issue of the Journal of Clinical Oncology.

MCC has become a local pancreatic cancer referral center due to collaborative work with the UNMC pancreaticobiliary surgeon group, national Pancreatic Action Network (PAN-CAN) and the local expertise of its cancer team.

This issue

Hematologist/oncologist to join MCC in July

Dr. Soe Min Tun

Dr. Soe Min Tun plans to join the Morrison Cancer Center team in July 2021.

The hematologist/oncologist, who holds MBA and MS degrees, graduated from the University of Medicine in Yangon, Mayanmar, receiving his Medical Degree.

He completed his internal medicine residency at Woodhull Hospital in Brooklyn, New York. He is board-certified in Internal Medicine.

Currently, Dr. Tun is the chief fellow at the University of Massachusetts Medical School — Baystate in Springfield, MA. He will complete his hematology/medical oncology training in July 2021.

MLH Pathology features two abstracts

The Mary Lanning Healthcare Pathology Department had two abstracts accepted for presentation at the College of American Pathologists (CAP) meeting. The abstracts also will be published in the Archives of Pathology.

The first presentation focuses on reduction of surgical pathology turnaround time. The second, a collaborative work with the Morrison Cancer Center, offers an innovative method for consolidating molecular pathology data.

Adam Horn

Progressive Reduction of Surgical Pathology Turnaround Time in a Community Setting: A Multi-Modal Approach. **Brett Havel, BS, MLT(ASCP)CM; Dianna Uhrich, HT(ASCP); Terri Brown, MHA, MT(ASCP), LSSGB; Whitney Wedel, MD; Nick Lintel, MD; Adam Horn, MD (ahorn@marylanning.org).**

Consolidating Molecular Pathology Data: A Low-Cost Composite Report Prototype. **Adam Horn, MD (ahorn@marylanning.org); Lisa McCormick, MT(ASCP); Whitney Wedel, MD; Nick Lintel, MD; Mehmet S. Copur, MD; Shari Fiala, CTR; Sally Molnar, MBA, BS, RT(R)(M).**

MCC recognized for patient experience

The Morrison Cancer Center was recognized for Most Improved Department or Clinic in Patience Experience.

The award is for the first quarter of 2020, and was presented during the HCAHPS recognition on July 8.

The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey is a national, standardized, publicly reported survey of patients' perspectives of hospital care. It measurers patients' perceptions of their hospital experience. This allows valid comparisons to be made across hospitals locally, regionally and nationally.

The Morrison Cancer Center outpatient oncology team is pictured.

Medscape interviews Dr. Copur

Dr. M. Sitki Copur recently was interviewed by Medscape author, Dr. Veronica Hackethal and the cancernetwork.

Dr. Hackethal asked Dr. Copur to discuss BRCA 1/2 mutated breast cancer and controversies surrounding the universal molecular testing on all breast cancer patients.

Medscape is a national/international organization providing access to medical information and continuing medical education for physicians and health professionals.

Dr. Hackethal, MD, MSC, is a medical journalist based in New York City. The interview was published on the Medscape website on July 21. The link for the article is https://www.medscape.com/viewarticle/934294

Following the Medscape article, Dr. Copur was invited to do a video interview to discuss Multi-Gene Panel Testing in cancer. The link to the video was posted on the cancernetwork and placed on the Medical World News website of MJH life sciences.

https://www.cancernetwork.com/view/mehmet-copur-md-on-multi-gene-panel-testing-for-the-general-population

MCC contributes to ASCO online library

Dr. M. Sitki Copur recently contributed to the ASCO Research Community Forum (RCF) online library's first section, *Basic Requirements for Starting A Research Site.*

ASCO RCF provides a forum for researchers to share best practices, identify challenges to conducting clinical research and brainstorm effective strategies and solutions. Its library is now moving to a pdf format, where resources are housed in a single, searchable document.

Members of the research community can access resources developed by RCF year-round to address challenges in conducting and managing clinical trials.

Resources include the ASCO Toolkit of Resources on the Business of Clinical Trials, ASCO Insurance Coverage of Clinical Trials tool, ASCO Research Program Quality Assessment Tool, ASCO Clinical Trial Workload Assessment tool, Research Contract Negotiation Resources, a Clinical Trial Resource library and Topic Summaries and an online forum to connect the research community.

For more information, see https://connection.asco.org/magazine/society-member-news/take-advantage-asco-research-community-forum-resources-2019

Copur interviewed about COVID-19 article

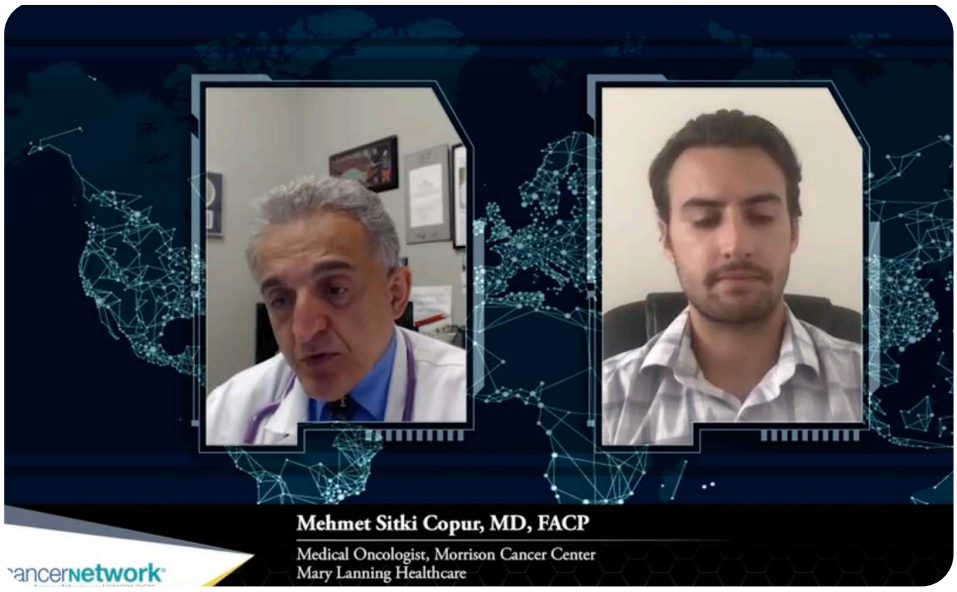
Dr. M. Sitki Copur recently was interviewed about an article he authored, "COVID-19 and Clinical Trials."

The article was published in the July issue of ONCOLOGY journal. He was invited to do the video interview, during which he discussed his thoughts. The interview was broadcast on the Medical World News website of MJH life sciences.

The ASCO Research Community Forum then posted the interview on its website: https://myconnection.asco.org/communities/community-home?CommunityKey=273b9459-6ef4-4d7b-8cdc-40c3f938a913

Links to both the podcast and broadcast posts are:

Broadcast: https://www.cancernetwork.com/view/mehmet-sitki-copur-md-on-inadequacies-of-the-clinical-trials-system-highlighted-by-covid-19 [cancernetwork.com]



Podcast: https://www.cancernetwork.com/view/oncology-peer-review-on-the-go-clinical-trials-system-and-the-covid-19-pandemic [cancernetwork.com]

Letter of intent accepted

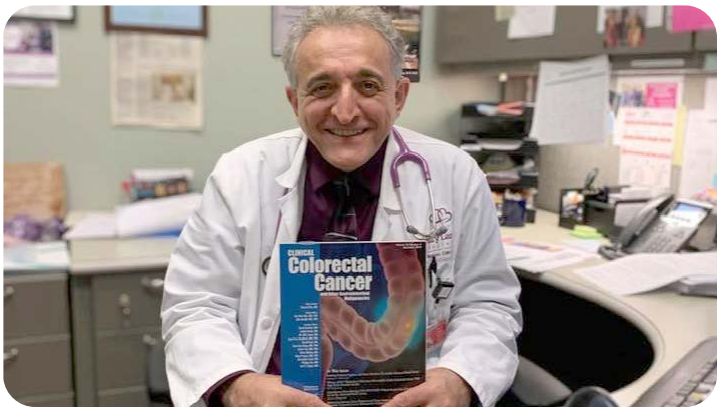
The Patient Centered Outcomes Research Institute (PCORI) accepted a collaborative grant application letter of intent from the Morrison Cancer Center and the University of Nebraska Medical Center.

PCORI was established as part of the US Patient Protection and Affordable Care Act of 2010 to fund patient-centered, comparative clinical effectiveness research. It extended the concept of clientele-centeredness from healthcare delivery to healthcare research. The project will evaluate implementation of patient-defined treatment success and preferences based on a prior pilot study in lung cancer, in which Dr. Copur was involved.

Dr. Copur continues as journal's associate editor

Dr. M. Sitki Copur recently accepted another three-year term as the associate editor of the *Clinical Colorectal Cancer* journal.

Dr. Copur has served on the editorial board of the journal since its inception. The journal is devoted to manuscripts that focus on early detection/screening, diagnosis, prevention and treatment of colorectal cancer and other gastrointestinal cancers, including pancreatic, liver, gastric/gastroesophageal and biliary. The journal emphasizes recent scientific developments and original peer-reviewed manuscripts. Specific areas of interest include original reports on clinical research and/or translational research and translational correlative science related to clinical trials. This includes multidisciplinary therapeutic fields related to colorectal cancer and other gastrointestinal cancers.



Pink Night at the Oregon Trail Rodeo

Members of the Morrison Cancer Center team (pictured above) attended Pink Night at the Oregon Trail Rodeo on August 22.

The Oregon Trail Rodeo Association raises money based on the number of audience members who wear pink to the event. Association members presented MCC with a check for $1,150 during the evening.

All of the funds raised will be used locally, helping cancer patients with expenses throughout the year.

Second advisory board meeting takes place

Dr. M. Sitki Copur, a member of the Community Advisory Board of the Fred and Pamela Buffett Cancer Center, met with the group for its second meeting on September 9.

The Fred and Pamela Buffett Cancer Center is the only National Cancer Institute (NCI)-designated cancer center in Nebraska and one of only 71 in the United States. NCI-designated cancer centers are recognized for their scientific leadership in laboratory and clinical research, in addition to serving their communities and the broader public.

Dr. Copur co-authors NCI Consensus Statement

Dr. M Sitki Copur served on a panel of multidisciplinary experts that helped summarize current data for the Colon and Rectal-Anal Task forces of the National Cancer Institute.

The data involved an increasing number of studies describing the potential uses of circulating tumor DNA (ctDNA) in the care of colorectal cancer patients.

The panel focused on four key areas in which ctDNA has the potential to change clinical practice, including the detection of minimal residual disease, management of patients with rectal cancer, monitoring responses to therapy and tracking clonal dynamics in response to targeted therapies.

Potentially Practice Changing DATA

Avoiding Peg-Filgrastim Prophylaxis during the Paclitaxel Portion of the Dose-Dense Doxorubicin-Cyclophosphamide and Paclitaxel Regimen: A Prospective Study

The use of growth factors adds considerable expense and some toxicity to adjuvant breast cancer chemotherapy.

The feasibility and safety of omitting routine peg-filgrastim use during the paclitaxel portion of the dose-dense doxorubicin-cyclophosphamide–paclitaxel regimen was evaluated.

This was a prospective, single-arm study in which patients 18 to 65 years of age who completed 4 cycles of dose-dense doxorubicin-cyclophosphamide for stage I-III breast cancer received paclitaxel 175 mg/m2 every 2 weeks. Peg-filgrastim was administered after paclitaxel only if patients had had febrile neutropenia in a prior cycle or at investigator discretion if patients had infections or treatment delays of one week.

Once a patient received peg-filgrastim, it was administered in all future cycles. The primary end point was the rate of paclitaxel completion within 7 weeks from cycle 1 day 1 to cycle 4 day 1. If 100 out of 125 patients completed 4 cycles of paclitaxel without dose delays the regimen was considered feasible.

The enrollment goal of 125 patients was met. Median age was 46 years (range, 21-65 years), and 112 patients (90% [95% CI, 83% to 94%]) completed dose-dense paclitaxel within 7 weeks. Omission of peg-filgrastim was not causally related to non-completion of paclitaxel in any patients. The most common reasons for dose reduction or delays were non hematologic. One patient experienced febrile neutropenia but was able to complete paclitaxel on time. Eight patients (6.4%) received peg-filgrastim during the trial.

Overall, peg-filgrastim was administered in only 4.3% of paclitaxel cycles. Omission of routine peg-filgrastim during dose-dense paclitaxel according to a prespecified algorithm seems to be safe and feasible and was associated with a 95.7% reduction in the use of peg-filgrastim relative to the current standard of care.

Reference: Vaz-Luis I et al. J Clin Oncol 2020; 38:2390-2397.

Potentially Practice Changing DATA

Five-Year Analysis of Adjuvant Dabrafenib plus Trametinib in Stage III Melanoma

In the previously reported primary analysis of this phase 3 trial, 12 months of adjuvant dabrafenib plus trametinib resulted in significantly longer relapse-free survival than placebo in patients with resected stage III melanoma with BRAF V600E or V600K mutations.

To confirm the stability of the relapse-free survival benefit, longer-term data were needed. Authors randomly assigned 870 patients who had resected stage III melanoma with BRAF V600E or V600K mutations to receive 12 months of oral dabrafenib (at a dose of 150 mg twice daily) plus trametinib (2 mg once daily) or two matched placebos.

The primary end point was relapse-free survival. Five-year results for relapse-free survival and survival without distant metastasis as the site of the first relapse were reported. Overall survival was not analyzed, since the required number of events to trigger the final overall survival analysis had not been reached.

The minimum duration of follow-up was 59 months (median patient follow-up, 60 months for dabrafenib plus trametinib and 58 months for placebo). At 5 years, the percentage of patients who were alive without relapse was 52% (95% confidence interval [CI], 48 to 58) with dabrafenib plus trametinib and 36% (95% CI, 32 to 41) with placebo (hazard ratio for relapse or death, 0.51; 95% CI, 0.42 to 0.61).

The percentage of patients who were alive without distant metastasis was 65% (95% CI, 61 to 71) with dabrafenib plus trametinib and 54% (95% CI, 49 to 60) with placebo (hazard ratio for distant metastasis or death, 0.55; 95% CI, 0.44 to 0.70). No clinically meaningful between-group difference in the incidence or severity of serious adverse events was reported during the follow-up period. In the 5-year follow-up of this phase 3 trial involving patients who had resected stage III melanoma with BRAF V600E or V600K mutations, 12 months of adjuvant therapy with dabrafenib plus trametinib resulted in a longer duration of survival without relapse or distant metastasis than placebo with no apparent long-term toxic effects.

Reference: Dummer R et al. N Eng J Med September 2, 2020DOI: 10.1056 / NEJMoa 2005493 2020

Potentially Practice Changing DATA

Veliparib with carboplatin and paclitaxel in BRCA-mutated advanced breast cancer (BROCADE3): a randomized, double-blind, placebo-controlled, phase 3 trial

BRCA1 or BRCA2-mutated breast cancers are sensitive to poly (ADP-ribose) polymerase (PARP) inhibitors and platinum agents owing to deficiency in homologous recombination repair of DNA damage.

In this trial, authors compared veliparib versus placebo in combination with carboplatin and paclitaxel, and continued as monotherapy if carboplatin and paclitaxel were discontinued before progression, in patients with HER2-negative advanced breast cancer and a germline BRCA1 or BRCA2 mutation. Eligible patients (aged ≥18 years) had deleterious germline BRCA1 or BRCA2 mutation-associated, histologically or cytologically confirmed advanced HER2-negative breast cancer an Eastern Cooperative Oncology Group performance status of 0–2, and had received up to two previous lines of chemotherapy for metastatic disease. Patients were randomly assigned (2:1) to carboplatin (area under the concentration curve 6 mg/mL per min intravenously) on day 1 and paclitaxel (80 mg/m 2 intravenously) on days 1, 8, and 15 of 21-day cycles combined with either veliparib (120 mg orally twice daily, on days –2 to 5) or matching placebo. If patients discontinued carboplatin and paclitaxel before progression, they could continue veliparib or placebo at an intensified dose (300 mg twice daily continuously, escalating to 400 mg twice daily if tolerated) until disease progression.

Patients in the control group could receive open-label veliparib monotherapy after disease progression. In the intention-to-treat population (n=509), 337 patients were assigned to receive veliparib plus carboplatin–paclitaxel (veliparib group) and 172 were assigned to receive placebo plus carboplatin–paclitaxel (control group). Median follow-up at data cutoff (April 5, 2019) was 35·7 months (IQR 24·9–43·6) in the veliparib group and 35·5 months (23·1–45·9) in the control group. Median progression-free survival was 14·5 months (95% CI 12·5–17·7) in the veliparib group versus 12·6 months (10·6–14·4) in the control group (hazard ratio 0·71 [95% CI 0·57–0·88], p=0·0016). Serious adverse events occurred in 115 (34%) patients in the veliparib group versus 49 (29%) patients in the control group. There were no study drug-related deaths. The addition of veliparib to a highly active platinum doublet, with continuation as monotherapy if the doublet were discontinued, resulted in significant and durable improvement in progression-free survival in patients with germline BRCA mutation-associated advanced breast cancer. These data indicate the utility of combining platinum and PARP inhibitors in this patient population.

Reference: Dieras V et al. Lancet Oncol August 27, 2020.DOI:https://doi.org/10.1016/S1470-2045(20)30447-2

Potentially Practice Changing DATA

Timing and delay of radical prostatectomy do not lead to adverse oncologic outcomes: results from a large European cohort at the times of COVID-19 pandemic

The current COVID-19 pandemic is transforming urologic practice and most urologic societies recommend to defer any surgical treatment for prostate cancer (PCa) patients.

It is unclear whether a delay between diagnosis and surgical management (i.e., surgical delay) may have a detrimental effect on oncologic outcomes of PCa patients.

The aim of this study was to assess the impact of surgical delay on oncologic outcomes. Data of 926 men undergoing radical prostatectomy across Europe for intermediate and high-risk PCa according to EAU classification were identified. Multivariable analysis using binary logistic regression and Cox proportional hazard model tested association between surgical delay and upgrading on final pathology, lymph-node invasion (LNI), pathological locally advanced disease (pT3–4 and/or pN1), need for adjuvant therapy, and biochemical recurrence. Kaplan–Meier analysis was used to estimate BCR-free survival after surgery as a function of surgical delay using a 3 month cut-off. Median follow-up and surgical delay were 26 months (IQR 10–40) and 3 months (IQR 2–5), respectively.

Authors did not find any significant association between surgical delay and oncologic outcomes when adjusted to pre- and post-operative variables. The lack of such association was observed across EAU risk categories. Delay of several months did not appear to adversely impact oncologic results for intermediate and high-risk PCa, and support an attitude of deferring surgery in line with the current recommendation of urologic societies.

Reference: Diamand, R et al. World J Urol (2020). https://doi.org/10.1007

Publications since our last issue

• Dasari, A., Morris, V., Allegra, C.J., Benson, A., Boland, Chung K., **Copur, M.S.**, et al. Circulating Tumor DNA Applications and Integration in Colorectal Cancer: An NCI Colon & Rectal-Anal Task Forces Whitepaper. Nature Reviews Clinical Oncology. Nat Rev Clin Oncol (2020). https://doi.org/10.1038/s41571-020-0392-0 **(Published)**

• Sohal, DPS, Kennedy E, Cinar P, Conroy T, **Copur, M.S.**, et al. Metastatic Pancreatic Cancer: ASCO Guideline Update J Clin Oncol 2020. August 5, 2020: DOI https://doi.org/10.1200/JCO.20. 01364 **(Published)**

• **Copur, M.S.**, Talmon, G., **Wedel, W., Hart, J.,** Merani, S., Vargas, L. Hereditary vs Familial Pancreatic Cancer; Associated Genetic Syndromes and Clinical Perspective. Oncology (Williston Park). 2020;34:6 https://www.cancernetwork.com/view/hereditary-vs-familial-pancreatic-cancer-associated-genetic-syndromes-and-clinical-perspective **(Published)**

• Hackethal V. , 'Knowledge Is Power':Knowing BRCA1/2 Status Tied to Survival. Medscape. July 21 2020. https://www.medscape.com/viewarticle/934294#vp_2 **(Published)**

• **Copur, M.S.** Ineptitude of Clinical Trials System Highlighted by COVID-19 Pandemic. Perspective Article. Oncology (Williston Park). 2020; 34:7 https://www.cancernetwork. com/view/ineptitude -of-clinical-trials-system-highlighted-by-covid-19-pandemic **(Published)**

• **Copur, M.S.,** ASCO 2020: Gastrointestinal Cancer Presentations Relevant to Clinical Practice. Oncology (Williston Park) July 14, 2020;34:7 https://www.cancernetwork.com/view/asco-2020-gastrointestinal-cancer-presentations-relevant-to-clinical-practice **(Published)**

• **Copur, M.S.**, Cushman-Vokoun, A.M., Delaney, A., Padussis, J., **Wedel, W.**, Lauer, S., Locally Advanced Gastrointestinal Stromal Tumor in a 33-Year Old Woman Desirous to Have Children. Oncology (Williston Park). 2020; 34:8 https://www.cancernetwork.com/view/locally-advanced-gastrointestinal-stromal-tumor-in-a-33-year-old-woman-seeking-to-conceive **(Published)**

• **Copur, M.S., Lackner R., Rodriguez P., Horn A., Faris S., Zusag T.** Recurrent EGFR-Mutated Non–Small Cell Lung Cancer Discovered by Abnormal Mammogram:Adjuvant/Frontline Metastatic Management Options. Oncology (Williston Park). 2020; 34:9 **(Accepted for publication)**

• **Dianna Uhrich, HT(ASCP); Terri Brown, MHA, MT(ASCP), LSSGB; Whitney Wedel, MD; Nick Lintel, MD; Adam Horn, MD** Progressive Reduction of Surgical Pathology Turnaround Time in a Community Setting: A Multi-Modal Approach. **(Accepted for publication)**

• **Adam Horn, MD; Lisa McCormick, MT(ASCP); Whitney Wedel, MD; Nick Lintel, MD; Mehmet S. Copur, MD; Shari Fiala, CTR; Sally Molnar, MBA, BS, RT(R)(M).** Consolidating Molecular Pathology Data: A Low-Cost Composite Report Prototype. **(Accepted for publication)**

• Chu E, Harrold LJ, **Copur, M.S.** Chemotherapeutic and Biologic Drugs. In: Physicians Cancer Chemotherapy Drug Manual. Chu E, De Vita ed. 2021.**(Accepted for publication)**

• Harrold LJ, **Copur, M.S.** , Chu E. Guidelines for Chemotherapy and Dosing Modifications. In: Physicians Cancer Chemotherapy Drug Manual. Chu E, DeVita ed.2012. **(Accepted for publication)**

• **Copur, M.S.,** Harrold LJ, Chu E. Common Chemotherapy Regimens in Clinical Practice. In: Physicians Cancer Chemotherapy Drug Manual. Chu E, DeVita ed.2021.**(Accepted for publication)**

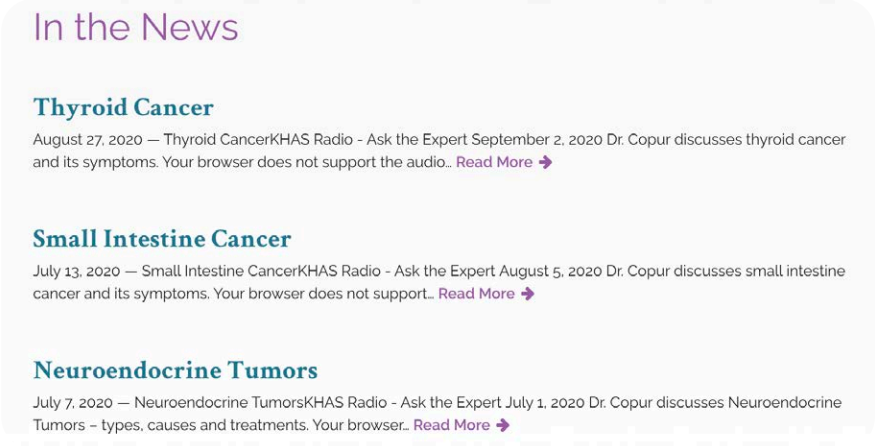
• Maguire W, **Copur, M.S.**, Harrold LJ, Chu E. Antiemetic Agents for the treatment of Chemotherapy-Induced Nausea and Vomiting. In: Physicians Cancer Chemotherapy Drug Manual. Chu E, DeVita ed. 2012. **(Accepted for publication)**

New 'Ask the Expert' topics posted

The KHAS radio "Ask the Expert" segments for October, November and December can be found on the Mary Lanning website.

Topics for the quarter include a Breast Cancer Update for October Breast Cancer Awareness Month, Myelodysplastic Syndromes for November and Hepatocellular Cancer for December. The interviews are broadcast on the first Wednesday and third Friday of each month on KHAS (1230 AM) radio.

www.marylanning.org/our-services/cancer-care/in-the-news/



FDA hematology/oncology drug approvals since last issue

• FDA approved **Azacitidine** tablets (ONUREG®, Celgene Corporation) for continued treatment of patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy. **September 1, 2020.**

• FDA approved **Carfilzomib** (KYPROLIS, Onyx Pharmaceuticals, Inc.) and Daratumumab (DARZALEX, Janssen Biotech, Inc.) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. **August 20, 2020.**

• FDA approved **Belantamab Mafodotin-blmf** (Blenrep, GlaxoSmithKline) for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. **August 5, 2020.**

• FDA approved **Tafasitamab-cxix** (MONJUVI, MorphoSys US Inc.), a CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant. **July 31, 2020.**

• FDA approved **Atezolizumab** (Tecentriq, Genentech, Inc.) in combination with Cobimetinib and Vemurafenib for patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. **July 30, 2020.**

• FDA granted accelerated approval to **Brexucabtagene Autoleucel** (TECARTUS, Kite, a Gilead Company), a CD19-directed genetically modified autologous T cell immunotherapy, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). **July 24, 2020.**

• FDA approved an oral combination of **Decitabine** and **Cedazuridine** (INQOVI, Astex Pharmaceuticals, Inc.) for adult patients with myelodysplastic syndromes (MDS). **July 7, 2020.**

• FDA approved **Avelumab** (BAVENCIO, EMD Serono, Inc.) for maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. **June 30, 2020.**

• FDA approved **Pembrolizumab** (KEYTRUDA, Merck & Co.) for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer. **June 29, 2020.**

• FDA approved a new fixed-dose combination of **Pertuzumab, Trastuzumab,** and **hyaluronidase–zzxf** (PHESGO, Genentech, Inc.) **June 29, 2020.**

• FDA approved **Pembrolizumab** (KEYTRUDA, Merck & Co., Inc.) for patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation. **June 24, 2020.**

• FDA granted accelerated approval to **Selinexor** (XPOVIO, Karyopharm Therapeutics) for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy. **June 22,2020.**

• FDA granted accelerated approval to **Tazemetostat** (TAZVERIK, Epizyme, Inc.), an EZH2 inhibitor, for adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and for adult patients with R/R FL who have no satisfactory alternative treatment options. **June 18, 2020.**

• FDA granted accelerated approval to **Pembrolizumab** (KEYTRUDA, Merck & Co., Inc.) for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB H) (≥10 mutations/megabase (mut/Mb)) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. **June 16, 2020.**

• FDA extended the indication of **Gemtuzumab ozogamicin** (MYLOTARG, Wyeth Pharmaceuticals LLC) for newly-diagnosed CD33-positive acute myeloid leukemia (AML) to include pediatric patients 1 month and older. **June 16, 2020.**

• FDA granted accelerated approval to **Lurbinectedin** (ZEPZELCA, Pharma Mar S.A.) for adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. **June 15, 2020.**

• FDA approved **Nivolumab** (OPDIVO, Bristol-Myers Squibb Co.) for patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy. More Information. **June 10, 2020.**

• FDA approved **Ramucirumab** (CYRAMZA, Eli Lilly and Company) in combination with Erlotinib for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations. **May 29, 2020.**

• FDA approved **Atezolizumab** in combination with Bevacizumab (TECENTRIQ and AVASTIN, Genentech Inc.) for patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy. **May 29, 2020.**

• FDA approved the combination of **Nivolumab** (OPDIVO, Bristol-Myers Squibb Co.) plus Ipilimumab (YERVOY, Bristol-Myers Squibb Co.) and 2 cycles of platinum-doublet chemotherapy as first-line treatment for patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. **May 26, 2020.**

• Food and Drug Administration approved **Brigatinib** (ALUNBRIG, ARIAD Pharmaceuticals Inc.) for adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. **May 22, 2020.**

MCC staff join a patient's friends and family in cheering her on after her last appointment at MCC recently.

Mary Lanning
HEALTHCARE
Morrison Cancer Center

815 N. Kansas Avenue
Hastings, NE 68901

Morrison Cancer Center

815 N. Kansas Ave.
Hastings, NE
402-460-5899